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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,214	02/22/2002	Roger D.A. Lipman	47915/A23	1358

81029 7590 07/01/2011

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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
07/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/069,214	LIPMAN, ROGER D.A.	
	Examiner	Art Unit	
	Isis Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-13,15 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7, 9-13, 15, 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 04/26/2011.

Claims 1-5, 7, 9-13, 15, 21-23 are pending and included in the prosecution.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorensen et al. (US 4,231,369) in view of Kishi et al. (JP 63-280013), both references are of record.

Applicant Claims

Applicant's claim 1 is directed to a pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin.

Claim 22 is directed to a pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of a hydrocolloid composition consisting essentially of a cyclodextrin and a hydrocolloid other than cyclodextrin.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Sorensen teaches an adhesive sealing material for use in connection to ostomy devices composed of continuous rubber phase and hydrocolloid dispersed in the continuous phase, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-60). Example O, Table III, shows that the styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition, which read on the instantly claimed amounts because claim 4 recites up to 50% polyisobutylene and claim 5 recites up to 15% of styrene polymer. The hydrocolloid is a mixture of more than one

hydrocolloid in an amount ranges from 48-56 % (col.8, lines 52-54; Example O, Table III). The composition further comprises oils, medicaments, or bactericides (col.6, lines 33, 45-47). The composition is supplied by release liner, i.e. substrate (col.9, lines 1-2).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Sorrensen teaches mixture of hydrocolloids, however the reference does not teach cyclodextrin among the hydrocolloids as claimed by claims 1 and 22, the amount of cyclodextrin as claimed by claims 2 and 3, or the material of the substrate as claimed in claim 15.

Kishi teaches plaster that removes body odor and stretch when skin stretches and does not cause a moist skin. The plaster comprises a base substrate layer and adhesive layer. The adhesive layer comprises rubber adhesive such as styrene-isoprene-styrene copolymer containing ≥ 3% cyclodextrin, and more preferably ≥ 5%, and generally from 3-40% of the adhesive composition, or combination of cyclodextrin and softening agent such as guar gum, karaya gum, pectin and carboxymethyl cellulose, which are hydrocolloids other than cyclodextrin claimed by applicants. The base substrate can be polyester, which is used by applicant as backing material. (See abstract; page 4, 1st paragraph; page 5, 2nd and 3rd paragraphs; page 6; page 8, 1st paragraph). The reference does not disclose cyclodextrin as complexed, so it can be uncomplexed.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an adhesive composition useful for medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as taught by Sorensen, and replace one of the hydrocolloids in the hydrocolloid phase with 3-40% of cyclodextrin and apply the composition on a polyester substrate as taught by Kishi. One would have been motivated to do so because Kishi teaches that cyclodextrin in combination with another hydrocolloid incorporated in an adhesive composition applied on a polyester backing provides removal of body odor and stretching when skin stretches and does not cause a moist skin. One would reasonably expected formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin and another hydrocolloid that effectively removes unacceptable odors and meanwhile comfortable to the user.

Regarding the claimed amounts of hydrocolloids, cyclodextrin and adhesives, the amounts taught by the prior art overlap with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

4. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poulsen et al. (US 4,367,732) in view of Kishi et al. (JP 63-280013) both references are of record.

Applicant Claims

Applicant's claim 1 is directed to a pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin.

Claim 22 is directed to a pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of a hydrocolloid composition consisting essentially of a cyclodextrin and a hydrocolloid other than cyclodextrin.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Poulsen teaches a skin barrier comprises an adhesive layer comprising discontinuous hydrocolloid phase dispersed in a continuous phase comprising styrene copolymers and polyisobutylene (abstract; col.5, lines 24-26, 49; col.6, lines 35-36; col.8, lines 31-42, 62-64). The adhesive composition further comprises bacteriostatic or fungicidal agents (col.6, line 59). The hydrocolloid phase comprises at least one hydrocolloid, and forms 10-55% of the composition of the adhesive layer (col.8, lines 53-55; col.9, lines 22-23). The styrene copolymer forms 10-40% of the continuous phase (col.9, line 16). The skin barrier further comprises a non-adhesive, water impervious film secured to the adhesive layer (col.3, lines 54-56).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Although Poulsen teaches mixture of hydrocolloids, however the reference does not teach cyclodextrin among the hydrocolloids as claimed by claims 1 and 22, the amount of cyclodextrin as claimed by claims 2 and 3, or the material of the substrate as claimed in claim 15.

Kishi teaches plaster that removes body odor and stretch when skin stretches and does not cause a moist skin. The plaster comprises a base substrate layer and adhesive layer. The adhesive layer comprises rubber adhesive such as styrene-isoprene-styrene copolymer containing ≥ 3% cyclodextrin, and more preferably ≥ 5%, and generally from 3-40% of the adhesive composition, or combination of cyclodextrin and softening agent such as guar gum, karaya gum, pectin and carboxymethyl

cellulose, which are hydrocolloids other than cyclodextrin claimed by applicants. The base substrate can be polyester, which is used by applicant as backing material. (See abstract; page 4, 1st paragraph; page 5, 2nd and 3rd paragraphs; page 6; page 8, 1st paragraph). The reference does not disclose cyclodextrin as complexed, so it can be uncomplexed.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition for adhesive barrier comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as taught by Poulsen, and replace one of the hydrocolloids in the hydrocolloid phase with 3-40% of cyclodextrin and apply the composition on a polyester substrate as taught by Kishi. One would have been motivated to do so because Kishi teaches that cyclodextrin in combination with another hydrocolloid incorporated in an adhesive composition applied on a polyester backing provides removal of body odor and stretching when skin stretches and does not cause a moist skin. One would reasonably expected formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin and another hydrocolloid that effectively removes unacceptable odors and meanwhile comfortable to the user.

Regarding the claimed amounts of hydrocolloids, cyclodextrin and adhesives, the amounts taught by the prior art overlap with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 1-5, 7, 9-13, 15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipman (WO 99/14282) in view of Kishi et al. (JP 63-280013), both references are of record.

Applicant Claims

Applicant's claim 1 is directed to a pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin.

Claim 22 is directed to a pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising 0.1 to 65 wt %, based on the total composition, of a

hydrocolloid composition consisting essentially of a cyclodextrin and a hydrocolloid other than cyclodextrin.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Lipman teaches a pressure sensitive adhesive material comprising continuous phase of rubber comprising styrene copolymer and polyisobutylene; and a discontinuous phase comprising hydrocolloid (abstract). The discontinuous phase forms 15-70 wt % of the composition (page 11, first paragraph). The styrene copolymer forms 10-30 wt % of the composition, and the polyisobutylene forms 20-60 wt % of the composition (page 15, claims 1-4). Examples 1 and 2, page 13, shows that the composition comprising more than one hydrocolloid including CMC and pectin. The composition comprises bactericides (page 11, third paragraph). The adhesive composition is coated on non-adhesive waterproof film and used in adhesive barrier or dressing for medical use (page 16, claim 13).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Lipman teaches one or more hydrocolloids, however the reference does not teach cyclodextrin among the hydrocolloids as claimed by claims 1 and 22, the amount of cyclodextrin as claimed by claims 2 and 3, or the material of the substrate as claimed in claim 15.

Kishi teaches plaster that removes body odor and stretch when skin stretches and does not cause a moist skin. The plaster comprises a base substrate layer and adhesive layer. The adhesive layer comprises rubber adhesive such as styrene-isoprene-styrene copolymer containing ≥ 3% cyclodextrin, and more preferably ≥ 5%, and generally from 3-40% of the adhesive composition, or combination of cyclodextrin and softening agent such as guar gum, karaya gum, pectin and carboxymethyl cellulose, which are hydrocolloids other than cyclodextrin claimed by applicants. The base substrate can be polyester, which is used by applicant as backing material. (See abstract; page 4, 1st paragraph; page 5, 2nd and 3rd paragraphs; page 6; page 8, 1st paragraph). The reference does not disclose cyclodextrin as complexed, so it can be uncomplexed.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an adhesive barrier or dressing for medical use comprising composition comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising more than one hydrocolloid as taught by Lipman, and replace one of the hydrocolloids in the hydrocolloid phase with 3-40% of cyclodextrin and apply the composition on a polyester substrate as taught by Kishi. One would have been motivated to do so because Kishi teaches that cyclodextrin in combination with another hydrocolloid incorporated in an adhesive composition applied on a polyester

backing provides removal of body odor and stretching when skin stretches and does not cause a moist skin. One would reasonably expected formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin and another hydrocolloid that effectively removes unacceptable odors and meanwhile comfortable to the user.

Regarding the claimed amounts of hydrocolloids, cyclodextrin and adhesives, the amounts taught by the prior art overlap with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed 04/26/2011 have been fully considered but they are not persuasive.

Applicant disagrees with the Examiner's assertion that the combination of references discloses the present claimed invention. The Examiner states on page 4 of the Office Action that Sorenson discloses a hydrocolloid disperse in a continuous phase, i.e. forming discontinuous phase and cites to the abstract, col. 4, lines 30-31, 55-60 of Sorensen for support. Applicant asserts that these citations of Sorensen fail to

disclose wherein a hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin dispersed within a discontinuous phase of absorbent material. The present invention more specifically discloses that hydrocolloid adhesives have two phases a rubbery phase and a discontinuous phase of absorbent material. In the present invention, a hydrocolloid composition is dispersed within the discontinuous phase of the continuous phase. While Sorensen acknowledges a continuous phase, Applicant asserts it cannot be assumed that because of the disclosure of a continuous phase a hydrocolloid composition is dispersed within the discontinuous phase of a continuous phase. Sorensen discloses that the hydrocolloids are distributed as particles in the continuous "rubber" like phase of the gel-like composition, and not discontinuous phase. Sorensen discloses "to be required for a proper function as described above are retained in a rubber like composition having a hydrocolloid dispersed therein". Sorensen discloses that the hydrocolloids are in the continuous rubbery phase which teaches against that of the present invention. Applicant argues that Kishi fails to remedy the deficiencies of Sorensen and fails to disclose wherein a discontinuous phase comprises a hydrocolloid composition. Therefore, the combination of references fails to teach or suggest all of the claim limitations of the present invention.

In response to the above arguments, it is argued that the examiner does not rely on Sorensen for teaching cyclodextrin, rather the secondary reference Kishi teaches the cyclodextrin, or Sorensen would have been an anticipatory reference. One cannot attack the references individually wherein the rejection is based on combination of the

references. The examiner disagree with applicant's statement that "In the present invention, a hydrocolloid composition is dispersed within the discontinuous phase of the continuous phase." It is the examiner's position that the present claim 1 recites "A pressure-sensitive adhesive composition comprising a rubbery continuous phase with a discontinuous phase distributed therein, said discontinuous phase comprising.....hydrocolloid composition comprising an uncomplexed cyclodextrin and a hydrocolloid other than cyclodextrin." Therefore, broadest reasonable interpretation of the present claims is continuous rubbery phase and discontinuous phase dispersed/distributed in the rubbery phase, and this discontinuous phase comprises mixture of hydrocolloids including cyclodextrin. Unlike applicant's assertion that "the hydrocolloid composition is dispersed within the discontinuous phase", rather the discontinuous phase is distributed or dispersed in the continuous phase and this discontinuous phase comprises the hydrocolloid mixture. The present invention as described in page 1, last paragraph is: "Hydrocolloid adhesives are a unique kind of medically useful pressure sensitive adhesive. They have usually **two phases a rubbery phase which provides pressure sensitive tack, sometimes called "dry tack" and, dispersed within the continuous rubbery phase, a discontinuous phase** of absorbent material." Therefore, applicant disclosed the discontinuous phase as a disperse of absorbent materials in the rubbery phase, as taught by Sorensen. Sorensen teaches an adhesive sealing material for use in connection to ostomy devices composed of **continuous rubber phase and hydrocolloid dispersed in the continuous phase**, i.e. forming discontinuous phase (abstract; col.4, lines 30-31, 55-

60). Example O, Table III, shows that the styrene copolymer "Cariflex" forms 10.9% of the composition, and polyisobutylene forms 18.1 % of the composition. The hydrocolloid is a mixture of more than one hydrocolloid in an amount ranges from 48 to 56 % (col.8, lines 52-54; Example O, Table III). The only element missing from Sorensen is cyclodextrin that is taught by Kishi. Kishi suggested the use of cyclodextrin in combination with other hydrocolloid for incorporation in plaster to remove body odor, and this teaching would have suggested to one having ordinary skill in the art to include cyclodextrin taught by Kishi in the mixture of hydrocolloids taught by Sorensen that are used in wound dressing as set forth in this office action. Therefor the present invention as a whole is taught by the combined teachings of the cited prior art, and the present invention would have been prima facie obvious in the meaning of 35 U.S.C. 103(a).

Applicant disagrees with the Examiner's argument on page 5 of the Office action that "because Kishi fails to disclose the cyclodextrin as complexed, then it must be uncomplexed." The question of whether the requisite suggestion or motivation is present cannot be resolved on the basis of subjective belief, unknown authority, or general conclusions about what is "basic knowledge" or "common sense." In re Lee, 61 USPQ2d 1430, 1434-35 (Fed. Cir. 2002).

In response to this argument, it is argued that Kishi is silent regarding complexion of cyclodextrin, and cyclodextrin is only either complexed or uncomplexed and the reference teaches derivatives of cyclodextrin and does not prefer one form over the other, and this implies equivalency between both. Applicants failed to show unexpected

results obtained from using uncomplexed cyclodextrin over the complexed. Kishi teaches cyclodextrin and its derivatives, see for example last paragraph of page 5 and first paragraph of page 6. Derivatives of cyclodextrin reads on complexed cyclodextrin, so the reference suggested both complexed and uncomplexed. It had been decided by Courts that the indiscriminate selection of "some" among "many" is considered prima facie obvious. *In re Lemin,* 141 USPQ 814 (1964); *National Distillers and Chem. Corp. V. Brenner*, 156 USPQ 163. In the instant case the selection is only between two choices. Indeed, in that case selection is not among many, rather the genus size is very limited to complexed and uncomplexed cyclodextrin.

Applicant argues that as acknowledged by the Examiner on page 4 of the Office Action, although Sorensen teaches mixtures of hydrocolloids, Sorensen does not teach cyclodextrin among the hydrocolloids, and one skilled in the art would not substitute the cyclodextrin disclosed in Kishi for the hydrocolloid in Sorensen because Sorensen specifically discloses "the best mixture of hydrocolloids for use in the sealing material according to the invention is a mixture of approximately 36 parts by weight of sodium carboxymethyl cellulose to 16 parts by weight of guar gum". Furthermore, Applicant asserts that the suggested substitution is impermissible hindsight.

In response to this argument, it is argued that Sorensen suggested mixture of hydrocolloids, and preferred sodium carboxymethyl cellulose to and guar gum, however, it has been held that the examples and preferred embodiment do not considered superior and do not constitute a teaching away from broader disclosure or nonpreferred

embodiments. It has been held that disclosed examples and preferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). If Sorensen teaches cyclodextrin, it would have been anticipatory reference. One having ordinary skill in the art would have replaced one of the hydrocolloids taught by Sorensen by cyclodextrin taught by Kishi for the advantage taught by Kishi that cyclodextrin in combination with another hydrocolloid incorporated in an adhesive composition applied on a polyester backing provides removal of body odor and stretching when skin stretches and does not cause a moist skin. One would reasonably expected formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase comprising cyclodextrin mixed with other hydrocolloid that effectively removes unacceptable odors and meanwhile comfortable to the user.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case Kishi suggested the use of cyclodextrin in combination with other hydrocolloid for incorporation in plaster to remove body odor, and this teaching would have suggested to one having ordinary skill in the art to include cyclodextrin taught by Kishi in the mixture of hydrocolloids taught by Sorensen that are used in wound dressing as set forth in this office action. Motivation to combine the references is drawn from the teachings of the prior art and not from applicant's disclosure.

Applicant argues that Poulsen teaches away from utilizing a cyclodextrin as a component of a hydrocolloid composition unlike the present invention. As acknowledged by the Examiner on page 8 of the Office action, although Poulsen teaches mixture of hydrocolloids, the reference does not teach cyclodextrin among the hydrocolloids. Instead Poulsen discloses sodium carboxymethyl cellulose is preferred. Poulsen fails to disclose that a cyclodextrin is a suitable type of hydrocolloid that may be utilized and one skilled in the art would assume that a cyclodextrin could not be used as the hydrocolloid in Poulsen. Therefore one skilled in the art would not substitute the cyclodextrin disclosed in Kishi in the invention of Poulsen because cyclodextrin is not listed as a suitable hydrocolloid for the composition disclosed in Poulsen and the utilization of a cyclodextrin would change the principle of operation of Poulsen. Furthermore, in performing the obviousness inquiry under 35 U.S.C. §103, the

Examiner must avoid hindsight. Applicant asserts the Examiner is utilizing hindsight by combing the cyclodextrin of Kishi with the composition of Pouslen when Pouslen explicitly states a preferred hydrocolloid which is not a cyclodextrin. Applicant asserts that Pouslen in view of Kishi fails to render the present invention obvious under 103(a).

In response to these arguments, the examiner' position is nowhere in the reference Poulsen teaches away from the present invention, rather the reference teaches mixture of hydrocolloids. The reference does not teach any disadvantage of using cyclodextrin in order to be considered as teaches away. Even if the reference preferred carboxymethyl cellulose, it has been held that the examples and preferred embodiment do not considered superior and do not constitute a teaching away from broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994. Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994) it has been decided that "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The

degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant."

It is further noted that if Poulsen teaches cylcodextrin, it would have been an anticipatory reference and no need to combine with Kishi reference. Further, both cited references are analogous art. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992), and it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. In this case, both references are from the field of applicant's endeavor and further reasonably pertinent to the particular problem with which the applicant was concerned, which is wound dressings.

The present invention as whole is taught by the combined teachings of the prior art and would have been prima facie obvious in the meaning of U.S.C. 103 (a). One having ordinary skill in the art would have replaced one of the hydrocolloids taught by Poulsen by cyclodextrin taught by Kishi for the advantage taught by Kishi that cyclodextrin in combination with another hydrocolloid incorporated in an adhesive composition applied on a polyester backing provides removal of body odor and stretching when skin stretches and does not cause a moist skin. One would reasonably expected formulating adhesive composition useful for personal care and medical devices comprising continuous rubbery phase and discontinuous hydrocolloid phase

comprising cyclodextrin and another hydrocolloid that effectively removes unacceptable odors and meanwhile comfortable to the user.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, Kishi suggested the use of cyclodextrin in combination with other hydrocolloid for incorporation in plaster to remove body odor, and this teaching would have suggested to one having ordinary skill in the art to include cyclodextrin taught by Kishi in the mixture of hydrocolloids taught by Poulsen that are used in wound dressing as set forth in this office action. Motivation to combine the references is drawn from the teachings of the prior art and not from applicant's disclosure.

Applicant argues that the present invention is not obvious over the combination of Lipman and Kishi for the same reasons as stated in reference to Pouslen in view Kishi.

In response to the argument against Lipman in view of Kishi, the examiner hereby repeats the argument set forth in this office action regarding Poulsen and Kishi

and further repeats that the present invention as a whole is taught by the combined teachings of the references.

Finally, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged

claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims as a whole would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicant directs the Examiner to take note that similar claims were granted in the European application (EP 1206290) which corresponds to the present application. Reference US 4,231,369 (Sorensen) which was cited by the Examiner in the present application was also a reference cited in the European application. The European application was deemed allowable over Sorensen in Europe and Applicant earnestly solicits an identical response from the Examiner in the U.S. regarding this reference.

In response to this argument, it is argued that the rejection of record is over the combination of Sorensen in view of Kishi, and over Sorensen alone. Kishi was not cited by the European Patent Office. The present invention as a whole as defined by the claims would have been obvious over the combination of Sorensen in view Kishi in the meaning of U.S.C. 103 (a).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571)272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611